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Enhancing Communication Between Scientists, Government Officials, and the Lay Public: Advancing Science and Protecting the Public's Welfare through Better Multi-Stakeholder Interfacing

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I. INTRODUCTION

Science long has existed as a continuing quest for knowledge and advancement to improve the human condition. Where this quest approaches the “cutting-edge” limits of human experience, inherent risks and dangers arise both for the scientists conducting the research and the communities in which the research is performed. Protecting public welfare from health and safety threats is one of the fundamental responsibilities of government. Because most scientists believe that their research should be conducted without interference from codes, rules, regulations, or laws that might impinge their intellectual endeavors, there is often disagreement between scientists and government officials as to what truly is in the “best interests” of the public’s welfare. This disagreement came to a head during the recent controversy over the publication of two United States (“U.S.”) government-funded research studies on the H5N1 avian influenza virus.¹

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1. The National Science Advisory Board for Biosecurity (“NSABB”) faced this issue when the journals *Science* and *Nature* approached the Board seeking an opinion on whether to publish articles in which two separate scientific groups adapted the highly pathogenic

While similar conflicts between science and government have been documented and studied, there has been little discussion on how to better align the interests of science, government, and the public's welfare regarding the conduct of important research with inherent safety risks. Furthermore, the concerns of the general lay public and especially those living and working in the communities surrounding the sites where high-risk, cutting-edge research may be taking place often are drowned out during these conflicts. Better communication and collaboration between these stakeholders should allow scientists, government officials, and the lay public to voice their varied concerns. After understanding those concerns, all parties are able to begin addressing them in a mutually satisfactory manner, especially if such multi-stakeholder interfacing takes place as part of public planning, decision-making, and policy-making activities. Fortunately, models exist for the development of mechanisms to better align the interest of scientists conducting potentially dangerous biomedical research and the public's welfare. Through development of such frameworks, the relationship between scientists, government officials, and the lay public at the federal, state, and especially local and community levels of society can be dramatically enhanced. These models can be strengthened if supported by public policy and legal structures.

This article discusses various issues that should entice members of the lay public to actively engage and interface with scientific research institutions and government officials in their communities, and how such multi-stakeholder interfacing can be promoted as a matter of law and public policy. Following this Introduction, some background information on the purpose of scientific research and its impact on public welfare is provided in Part II, with a particular focus on biomedical research. In Part III, some key challenges in managing research programs are discussed, with particular emphasis on intentional and accidental releases of dangerous

H5N1 avian influenza virus to become permissible in ferrets, the closest laboratory model for human infection. Due in large part to a series of miscommunications, the NSABB initially recommended that the papers should be redacted to prevent potential irresponsible or nefarious actors from being able to replicate the research. However, as more information about the findings themselves became apparent, the NSABB reversed its position and the articles were published in full. Press Statement on the NSABB Review of H5N1 Research, Nat'l Insts. of Health (Dec. 20, 2011), available at <http://www.nih.gov/news/health/dec2011/od-20.htm>; Meeting of the National Science Advisory Board for Biosecurity to Review Revised Manuscripts on Transmissibility of A/H5N1 Influenza Virus, Nat'l Sci. Advisory Bd. for Biosecurity (Mar. 29- 30, 2012), available at http://oba.od.nih.gov/oba/biosecurity/PDF/NSABB_Statement_March_2012_Meeting.pdf; Statement by NIH Director Francis Collins, M.D., Ph.D. on the NSABB Review of Revised H5N1 Manuscripts, Nat'l Insts. of Health (Apr. 20, 2012), available at www.nih.gov/about/director/04202012_NSABB.htm.

biological agents into communities. Part IV discusses some existing legal and policy tools in the United States that are intended to protect the public from the research-related dangers described in Part III. In Part V, various aspects about the benefits of public participation in public affairs are discussed, as are examples of how public participation has been included in state and local efforts to enhance communication between scientists, government officials, and members of the lay public regarding issues related to dangerous biomedical research occurring in their common community. Part VI and the concluding remarks in Part VII attempt to synthesize the issues discussed in the preceding parts to support the argument that enhanced communication and collaboration between scientists, government officials, and the lay public provides the best way to ensure that scientific research on dangerous biological agents intended to promote and protect public welfare is conducted in a way that also promotes and protects public welfare.

II. BACKGROUND: SCIENTIFIC RESEARCH AND PUBLIC WELFARE

The ultimate goal of biomedical research is to improve the quality of life for members of society. Modern science has greatly advanced humanity's understanding of various biological functions and processes, thereby vastly enhancing its ability to provide better treatments for diseases and tools for improving human well-being. Seminal biomedical discoveries such as the use of penicillin as a potent antibiotic have led to significant reductions in morbidity and mortality and general improvements in overall quality of life in populations around the world.

Despite these remarkable achievements, many challenges remain in humanity's ability to prevent and cure a wide range of debilitating diseases, including a number of highly pathogenic and contagious infectious diseases that disproportionately affect adolescents and young adults. Infectious diseases also impose staggering burdens on societies worldwide in terms of morbidity and mortality rates and loss in productivity.² These burdens are exacerbated by socio-economic inequalities within societies and between nations: while many industrial nations have invested heavily in preventative medicine, developing countries have nowhere near the resources or capacity to match the serious impact that infectious diseases have on their respective

2. Ib Christian Bygbjerg, *Double Burden of Noncommunicable and Infectious Diseases in Developing Countries*, 337 *SCI.* 1499 (2012). It is estimated that African nations suffering from high rates of malaria have a 35% lower Gross Domestic Product ("GDP") compared to countries that are free from malaria. ROBERT CARLSON, *BIOLOGY IS TECHNOLOGY* 99 (2010).

societies.³ Furthermore, the ability to travel anywhere in the world within 24 hours has greatly increased biosecurity threats at the international stage, as was evident when a local outbreak of Severe Acute Respiratory Syndrome (“SARS”) in Hong Kong quickly turned into a global pandemic in 2003.⁴ The integration of the modern world economy means that the negative impacts of infectious diseases in one part of the world can have negative impacts on other parts within a short period of time.

These facts make a strong case for multi-national investment in research and other efforts to develop novel treatments for infectious diseases affecting people and societies around the world. The scope of such investment, however, depends in part on how individual societies and the international community determine the value and limitations of scientific research based on its comparative risks and benefits. This issue was at the center of the recent controversy that arose when scientists researching the highly pathogenic H5N1 avian influenza learned how to make the virus transmissible through the air.⁵

It is estimated that the human fatality rate among those infected with H5N1 is around 60%,⁶ which significantly exceeds the rate of mortality

3. Bygbjerg, *supra* note 2, at 1500. It is important to note that the economic burden of infectious diseases is neither constrained to developing countries, nor limited to neglected infectious diseases. Detrimental effects in lost productivity and wages also are evident in the United States with regard to the economic burden of influenza. In the United States, influenza epidemics result in roughly 610,660 life-years lost, 3.1 million hospitalization days, and 31.4 million outpatient visits during an average flu season. The direct medical costs average \$10.4 billion annually, and the total economic burden amounts to approximately \$87.1 billion annually. Noelle-Angelique M. Molinari et al., *The Annual Impact of Seasonal Influenza in the US: Measuring Disease Burden and Costs*, 25 *VACCINE* 5086 (2007).

4. Abu S.M. Abdullah et al., *Lessons from the Severe Acute Respiratory Syndrome Outbreak in Hong Kong*, 9 *EMERGING INFECTIOUS DISEASES* 1042 (2003), available at wwwnc.cdc.gov/eid/article/9/9/pdfs/03-0366.pdf. A pandemic may be defined as the global spread of an infectious disease that (1) spreads beyond a geographically limited area (e.g., a continent) and (2) has a higher rate of infected persons than a seasonal epidemic might have. This does not automatically imply that a pandemic is lethal compared to a localized epidemic. WORLD HEALTH ORGANIZATION [hereinafter WHO], *PANDEMIC INFLUENZA PREPAREDNESS AND RESPONSE* 27 (2009), available at http://whqlibdoc.who.int/publications/2009/9789241547680_eng.pdf; see also WHO, *WHO Pandemic Phase Descriptions and Main Actions by Phase*, available at http://www.who.int/influenza/resources/documents/pandemic_phase_descriptions_and_actions.pdf.

5. Sander Herfst et al., *Airborne Transmission of Influenza A/H5N1 Virus Between Ferrets*, 336 *SCI.* 1534 (2012); see also Masaki Imai et al., *Experimental Adaptation of an Influenza H5 HA Confers Respiratory Droplet Transmission to a Reassortant H5 HA/H1N1 Virus in Ferrets*, 486 *NATURE* 420 (2012).

6. Michael T. Osterholm & Nicholas S. Kelley, *Mammalian-Transmissible H5N1 Influenza: Facts and Perspective*, 3(2) *MBIO* e00045-12 (2012), available at <http://mbio.asm.org/content/3/2/e00045-12.full.pdf>.

measured during the 1918 Spanish influenza pandemic that reportedly killed one-third of the world's population at that time.⁷ To date, no effective treatments or vaccines have been developed that would reduce mortality and morbidity rates during a H5N1 pandemic.⁸ Consequently, any research on H5N1 that describes its adaptability to infect humans through forms other than direct contact (e.g., aerosol) raises significant concerns that the findings from such research could be adapted for malevolent applications intended to harm populations and societies (viz., a bioterrorism attack).⁹ Furthermore, such research brings an inherent risk of an accidental release of the biological agent being studied into the surrounding population and community.¹⁰

Such Dual-Use Research of Concern ("DURC") has come to the forefront of all debates regarding the importance of conducting cutting-edge research on highly pathogenic and deadly disease agents (i.e., "dangerous research") in recent years.¹¹ The central question in this debate is whether society is better off not studying certain diseases because the risk that such research will be used for sinister purposes outweighs the benefits it may have on responses to future pandemics.¹²

7. Terrence M. Tumpey et al., *Characterization of the Reconstructed 1918 Spanish Influenza Pandemic Virus*, 310 *SCI.* 77 (2005).

8. For definition of "pandemic," see *supra* note 4.

9. Special Issue: H5N1, 336(6088) *SCI.* 1473 (2012), available at www.sciencemag.org/content/336/6088.toc#SpecialIssue.

10. Joel O. Wertheim, *The Re-Emergence of H1N1 Influenza Virus in 1977: A Cautionary Tale for Estimating Divergence Times Using Biologically Unrealistic Sampling Dates*, 5(6) *PLoS ONE* e11184 (2010), available at www.plosone.org/article/info%3Adoi%2F10.1371%2Fjournal.pone.0011184. See also *infra* III(B).

11. See *infra* Part III.

12. The U.S. government considers biological-based threats to public welfare a public policy priority. A variety of activities support public health emergency management efforts at the federal, state, and local levels. These include statutorily-authorized initiatives to support research efforts aimed at developing medical countermeasures to dangerous pathogens and biological agents, as well as efforts to develop various preparedness, response, recovery, and mitigation capabilities for bioterrorist incidents or natural events involving such pathogens or biological agents. See, e.g., Project BioShield Act of 2004, Pub. L. No. 108-276, 118 Stat. 835 (2004); Office of Public Health, Emergency Preparedness Statement of Organization, Functions, and Delegations of Authority, 71 Fed. Reg. 38,403, (July 6, 2006); 2012 HHS PHEMCE Strategy and Implementation Plan, U.S. DEP'T HEALTH & HUMAN SERVS., www.phe.gov/Preparedness/mcm/phemce/Pages/strategy.aspx (last updated Dec. 10, 2012); Public Health Emergency Medical Countermeasures Enterprise, U.S. DEP'T HEALTH & HUMAN SERVS., <http://www.phe.gov/Preparedness/mcm/phemce/Pages/default.aspx> (last updated Dec. 10, 2012); Public Health Preparedness Capabilities: National Standards for State and Local Planning, U.S. CTRS. FOR DISEASE CONTROL & PREVENTION (2011), http://www.cdc.gov/phpr/capabilities/DSLRL_capabilities_July.pdf.

III. THE CHALLENGES OF MANAGING RESEARCH PROGRAMS

A. Dual-Use Research and Bioterrorism Concerns

In recent years, several non-state organizations have expressed their intent to harness cutting-edge technology to generate weapons of mass destruction to maximize physical and social harm and disruption in civilian populations. In some cases, such organizations actually have deployed biological agents against civilian populations. For example, in 1984, the Rajneesh Cult engaged in a mass salmonella poisoning campaign in an attempt to manipulate the outcome of local elections in Oregon.¹³ Between 1993 and 1995, the Aum Shinrikyo Sect in Japan attempted to release botulinum toxin and anthrax in Tokyo.¹⁴ More recently, Al-Qaeda publicly called for Weapons of Mass Destruction experts to join its cause by developing and testing biological weapons.¹⁵ Given this recent history, DURC has emerged as a legitimate concern for governments and the general public.

In response to these concerns, the research and peer-reviewed journal communities have grappled with whether to make findings from DURC publicly available on several occasions, based on a balancing of the benefits and risks. In the past decade alone, publications have controversially reported on how mousepox can be made more virulent with the addition of a single gene (2001);¹⁶ how the polio virus can be created through chemical synthesis (2002);¹⁷ and the genetic sequence of the virus underlying the 1918 Spanish influenza (2005).¹⁸

With scientific publications easily accessible worldwide through the Internet,¹⁹ a compelling argument can be made that published findings from

13. Philip Elmer-DeWitt, *America's First Bioterrorism Attack*, TIME, Sept. 30, 2001, available at <http://www.time.com/time/magazine/article/0,9171,176937,00.html>.

14. Archive: Nerve Gas Attack Shocks Tokyo (BBC News broadcast Mar. 1995), available at <http://www.bbc.co.uk/news/world-asia-18455007> (successfully releasing sarin gas in the Tokyo subway system on March 20, 1995).

15. Associated Press, *Pentagon: Al-Qaeda Pursuing Bio Weapons*, USA TODAY, May 23, 2003, available at http://usatoday30.usatoday.com/news/washington/2003-05-23-us-wmd_x.htm.

16. Ronald J. Jackson et al., *Expression of Mouse Interleukin-4 by a Recombinant Ectromelia Virus Suppresses Cytolytic Lymphocyte Responses and Overcomes Genetic Resistance to Mousepox*, 75 J. VIROLOGY 1205 (2001).

17. Jeronimo Cello et al., *Chemical Synthesis of Poliovirus cDNA: Generation of Infectious Virus in the Absence of Natural Template*, 297 SCI. 1016 (2002).

18. Tumpey et al., *supra* note 7.

19. U.S. National Library of Medicine & National Institutes of Health, PUBMED CENTRAL.COM, <http://www.ncbi.nlm.nih.gov/pmc/> (last updated Nov. 14, 2011) (many scientific articles, in addition to subscription-based online publications, are available online).

DURC will enable malefactors to use the information to create biological weapons. On the other hand, making information publicly available might spur the international community to develop more quickly the next generation of vaccines and pharmaceutical countermeasures, which will enable governments to prevent and respond effectively to man-made and natural bioterrorism attacks. As was evident from the recent H5N1 research controversy, this choice continues to weigh heavily on many minds as discussions persist on how much information about DURC findings should be divulged and disseminated to the public.²⁰

B. When the Bug Escapes the Lab: Accidental Releases of Biological Agents

The controversy over H5N1 research and DURC in general has almost exclusively focused on the danger of malefactors misusing the research for malevolent purposes. Attracting far less attention from the media are concerns related to accidental releases of deadly pathogens into the public from facilities researching such pathogens. These concerns are warranted, as there have been many instances when highly pathogenic agents (including influenza,²¹ smallpox,²² and plague²³) have been accidentally released from what were perceived as secure research facilities. In their fight for survival, pathogens have evolved to acquire the most effective mechanisms for transmission from one host to another. Therefore, unintentional introductions of a deadly pathogen into a community are a reality that threatens public health and safety. Because such an event most likely will be first discovered by community doctors treating patients who present initially with generic “flu-like” symptoms and then quickly develop more serious symptoms, mechanisms should be in place to educate and prepare communities where research on dangerous biological agents occurs for the possibility of an accidental release.

and free to the public through open access portals such as PubMed Central® (PMC)).

20. Bruce Alberts, Introduction: H5N1, 336(6088) *SCI.* 1521 (2012), available at <http://www.sciencemag.org/content/336/6088/1521.full.pdf>; see generally Special Issue: H5N1, *supra* note 9, at 1473.

21. Steve Connor, Did Leak From a Laboratory Cause Swine Flue Pandemic?, *THE INDEPENDENT*, June 30, 2009, available at www.independent.co.uk/news/science/did-leak-from-a-laboratory-cause-swine-flu-pandemic-1724448.html.

22. Robin McKie & Gabriel Stargardter, Smallpox Virus: Crunch Time for the Fate of a Global Killer, *THE OBSERVER*, Feb. 12, 2011, available at www.guardian.co.uk/society/2011/feb/13/smallpox-virus-vector-health-terror.

23. Julie Steenhuysen, Plague Researcher in Chicago Dies from Infection, *REUTERS* (Sept. 21, 2009, 1:32 PM), <http://www.reuters.com/article/2009/09/21/us-plague-death-idU5TRE58K3J120090921>.

DURC is fraught with both risks and opportunities. While research to enhance understanding of the deleterious effects of dangerous pathogens certainly falls within the public interest, ensuring that such research is conducted within the confines of sound scientific judgment and adequate security protects both the researchers and public at large. Due to the highly competitive nature of cutting-edge research, it is difficult to expect private or academic laboratories to be capable of policing themselves in this effort to maintain safety. Consequently, a clear (if limited) role for external governance of the safety requirements can surely be advantageous in certain defined circumstances. As discussed in Part IV, governmental authorities frequently provide such external governance by enacting laws and adopting public policies to protect the public from certain types of dangerous biomedical research.

IV. THE TOOLBOX OF PUBLIC HEALTH LAW: CURRENT LAWS AND POLICIES TO KEEP THE PUBLIC SAFE FROM DANGEROUS BIOMEDICAL RESEARCH

As the authors have asserted elsewhere, governments have a “legitimate interest [to] fulfill . . . their fundamental responsibility to protect their citizens that justifies taking reasonable actions to regulate activities . . . pos[ing] a significant threat to the general welfare of the public[.]”²⁴ Furthermore, governments “arguably have a compelling interest that justifies taking necessary actions to regulate such activities[.]”²⁵ Scientific experiments and research on dangerous biological agents are clear examples of such activities, given the potential threats to populations and communities posed by the misuse or accidents related to such research.²⁶ Consequently, governments at the federal, state, and local levels in the United States have taken various steps to address biological-based threats to the general public welfare as a matter of law and public policy.²⁷

The most comprehensive legal and policy efforts to keep the public safe from dangerous biomedical research have occurred at the federal level.²⁸

24. Patrick P. Rose et al., *Creating Monsters for the Greater Good of Humanity: Conflicting Interests of Science and Homeland Security*, J. EMERGENCY MGMT., Mar.-Apr. 2012 at 83, 87, available at www.mdchhs.com/articles-resources/articles/creating-monsters-greater-good-humanity-conflicting-interests-science-an; see *infra* Part V(A) and text accompanying notes 41-45 for an elaboration of arguments supporting this assertion.

25. Rose et al., *supra* note 24.

26. See Part III, *supra*.

27. Rose et al., *supra* note 24, at 87.

28. This makes sense, given the nationwide scope of the threat posed by DURC and given that the U.S. government (through the National Institutes of Health and other federal

Perhaps the most prominent of these federal efforts is the National Select Agent Program administered by the Centers for Disease Control and Prevention (“CDC”) of the U.S. Department of Health and Human Services (“HHS”) and the Animal and Plant Health Inspection Service (“APHIS”) of the U.S. Department of Agriculture (“USDA”).²⁹ This program is the creation of numerous federal statutes³⁰ and regulations³¹ governing various aspects of research on dangerous biological agents, including the possession, use, and transfer of the agents under the study, the entities and individuals conducting such research, and the types of experiments that can be performed.³² A number of states and local governments have enacted similar statutes and regulations.³³ Furthermore, a body of federal statutory

agencies) is the largest funder of biomedical research in the world. About NIH, NAT'L INSTS. OF HEALTH, <http://nih.gov/about/> (last reviewed Aug. 7, 2012).

29. NAT'L SELECT AGENT REGISTRY, <http://www.selectagents.gov> (last updated Jan. 14, 2013); CDC Select Agent Program, U.S. CTRS. FOR DISEASE CONTROL & PREVENTION, www.cdc.gov/phpr/documents/DSAT_brochure_July2011.pdf (July 2011). This program, which came into being in response to the April 1995 federal building bombing in Oklahoma City, was expanded after the Fall 2001 anthrax mailings. *Id.* at 2; see also About Us, NAT'L SELECT AGENT REGISTRY, <http://www.selectagents.gov/AboutUS.html> (last updated Jan. 8, 2013).

30. Agricultural Bioterrorism Protection Act of 2002, Pub. L. No. 107-188, 116 Stat. 647; Uniting and Strengthening America by Providing Appropriate Tools Required to Intercept and Obstruct Terrorism (USA PATRIOT ACT) Act of 2001, Pub. L. No. 107-56, § 817, 115 Stat. 272, 385-86 (codified as amended at 18 U.S.C. § 175b (2009)); Antiterrorism and Effective Death Penalty Act of 1996, Pub. L. No. 104-132, § 511, 110 Stat. 1214, 1284-85, amended by Public Health Security and Bioterrorism Preparedness and Response Act of 2002, Pub. L. No. 107-188, §201, 116 Stat. 594, 637-46.

31. 7 C.F.R. pt. 331 (2012) (implementing the provisions of the Agricultural Bioterrorism Protection Act of 2002 relating to the possession, use, and transfer of select agents and toxins that “have the potential to pose a severe threat to plant health or plant products.”); 9 C.F.R. pt. 121 (2012) (implementing the provisions of the Agricultural Bioterrorism Protection Act of 2002 relating to the possession, use, and transfer of select agents and toxins that “have the potential to pose a severe threat to . . . animal health, or to animal products.”); 42 C.F.R. pt. 73 (2012) (implementing the provisions of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 relating to the possession, use, and transfer of select agents and toxins that “have the potential to pose a severe threat to public health and safety . . .”).

32. For a review of these legal authorities, see Michael Greenberger et al., *Governance and Biosecurity: Strengthening Security and Oversight of the Nation’s Biological Agent Laboratories*, 13 DEPAUL J. HEALTH CARE L. 77 (2010); and Kavita Marfatia Berger, *The Role of Science in Preparedness and Response*, 6 U. ST. THOMAS L.J. 622, 628-32 (2009).

33. See, e.g., MD. CODE ANN., HEALTH-GEN. §17-601 to -605 (West 2012) (establishing the Maryland Biological Agents Registry Program); MD. CODE REGS. 10.10.11 (2012) (governing the Maryland Biological Agents Registry Program); CONN. GEN. STAT. ANN. § 19a-31a (West 2013) (establishing certain reporting requirements for institutions of higher education that operate Biosafety Level 3 laboratories in Connecticut); N.Y. PUB. HEALTH LAW § 3220-3223 (McKinney 2010) (regulating recombinant DNA experiments conducted in the State of New York); TENN. COMP. R. & REGS. § 1200-06-03-.11(1)(c)&(d)

and case law has been developed relating to restrictions on the publication and dissemination of findings from scientific research with implications for national security and public health and safety.³⁴

(2012) (requiring laboratories in Tennessee handling “cultures and stocks of infectious agents” to “develop, maintain, and implement policies and procedures” for handling infectious and hazardous waste); SEATTLE FIRE CODE §2701.1 and .7 (2009) (requiring the reporting of the locations of Biosafety Level 3 and 4 operations in Seattle to City fire officials); BOS., MASS., MUN. CODE § 17-9 (2013) (establishing guidelines for the regulation of the use of recombinant DNA in the City of Boston); BOS., MASS., PUBLIC HEALTH COMM’N REG., BIOLOGICAL LABORATORY REGULATIONS (2006), available at [www.bphc.org/boardofhealth/regulations/Forms%20%20Documents/regs_LabRegFinal_9-19-06\[1\].pdf](http://www.bphc.org/boardofhealth/regulations/Forms%20%20Documents/regs_LabRegFinal_9-19-06[1].pdf) (establishing permit requirements for Biosafety Level 3 or Level 4 biological research laboratory operating within the City of Boston); CAMBRIDGE, MASS., BIOSAFETY REGULATION (2009), available at http://cambridgepublichealth.org/Cambridge_Biosafety_Regulation_2009.pdf (establishing local regulation on the use of all biological agents and local prohibition on the use of biological agents requiring Biosafety Level-4 containment); CAMBRIDGE, MASS., MUN. CODE ch. 8.20 (2013), available at <http://cambridgepublichealth.org/services/regulatory-activities/biosafety/rDNA-ordinance.pdf> (establishing local regulation on the use of recombinant DNA technology); AMHERST, MASS., BOARD OF HEALTH, RECOMBINANT DNA TECHNOLOGY AND INFECTIOUS BIOLOGICAL AGENTS (2008), available at <http://ma-amherst3.civicplus.com/DocumentCenter/Home/View/2330> (local regulations on research involving the use of recombinant DNA or infectious biological agents or toxins, including a local prohibition on the use of recombinant DNA requiring Biosafety Level-4 containment measures); BELMONT, MASS., BOARD OF HEALTH, REGULATION FOR THE USE OF RECOMBINANT DNA MOLECULE TECHNOLOGY AND NON-RECOMBINANT INFECTIOUS AGENTS (2001), available at http://www.belmont-ma.gov/public_documents/belmontma_health/Regulations%20and%20Fees/S0188B2FF.0/BioTech%20Regs.pdf (establishing local regulations for the use of recombinant DNA molecule technology and non-recombinant infectious agents, including a local prohibition on the use of recombinant DNA, recombinant RNA, and infectious agents requiring Biosafety Level-3 or -4 containment measures), accord BEDFORD, MASS. BOARD OF HEALTH (2003) available at http://www.town.bedford.ma.us/index.php/regulations-a-policies/doc_view/711-bedford-regulations and TEWKSBURY, MASS. BOARD OF HEALTH ch. 8 (2011), available at http://www.tewksbury.net/Pages/TewksburyMA_Health/regs/Chapter%208%20for%20the%20use%20of%20Recombinant%20rDNA%20Technology.pdf. Biosafety Level (BSL) 3 and 4 are the most dangerous pathogens. See generally CTRS. FOR DISEASE CONTROL & PREVENTION, BIOSAFETY IN MICROBIOLOGICAL AND BIOMEDICAL LABORATORIES 38-59, HHS PUBLICATION NO. (CDC) 21-1112 (5th ed. 2009), available at <http://www.cdc.gov/biosafety/publications/bmb15/BMBL.pdf>; U.S. GOV’T ACCOUNTABILITY OFFICE, HIGH-CONTAINMENT LABORATORIES: NATIONAL STRATEGY FOR OVERSIGHT IS NEEDED, GAO-09-574 (Sept. 2009), available at www.gao.gov/assets/300/295543.pdf; U.S. GOV’T ACCOUNTABILITY OFFICE, HIGH-CONTAINMENT LABORATORIES: ASSESSMENT OF THE NATION’S NEED IS MISSING, GAO-13-466R (Feb. 2013), available at www.gao.gov/assets/660/652308.pdf.

34. For a review of this area of law, see, e.g., John D. Kraemer & Lawrence O. Gostin, *The Limits of Government Regulation of Science*, 335 *SCI.* 1047 (2012); Steve Keane, Note, *The Case Against Blanket First Amendment Protection of Scientific Research: Articulating a More Limited Scope of Protection*, 59 *STAN. L. REV.* 505 (2006); Brian J. Gorman, *Biosecurity and Secrecy Policy: Problems, Theory, and a Call for Executive Action*, 2 *I/S: J. L. & POL’Y FOR INFO. SOC’Y* 53 (2006); Brian J. Gorman, *Balancing National Security and Open Science: A Proposal for Due Process Vetting*, 7 *YALE J. L. & TECH.* 491 (2005).

The U.S. government also has made addressing DURC a national public policy priority, going as far as to issue the official United States Government Policy for Oversight of Life Sciences Dual Use Research of Concern in the aftermath of the recent controversy over the H5N1 studies.³⁵ Furthermore, the Secretary of HHS has renewed the charter for the National Science Advisory Board on Biosecurity (“NSABB”) until April 2014.³⁶ In its renewed charter, the NSABB is charged with continuing to “provide advice on and recommend specific strategies for the efficient and effective oversight of federally conducted or supported dual use biological research, taking into consideration both national security concerns and the needs of the research community to foster continued rapid progress in public health and agricultural research.”³⁷

Despite the existing legal and policy tools to address the hazards posed by potentially dangerous biomedical research, they generally reflect a “top-down” prescriptive approach from federal officials that favor engagement and participation from the scientific community but limit and even discourage engagement or participation from the lay public. As of January 2013, the 25 voting members of the NSABB included representatives from academia, the private and non-profit sectors, and retired military generals, but no representatives from the lay public.³⁸ Furthermore, although the U.S. government has solicited comments from the public on certain federal actions to regulate DURC and other research activities involving dangerous

35. U.S. GOV'T, UNITED STATES GOVERNMENT POLICY FOR OVERSIGHT OF LIFE SCIENCES DUAL USE RESEARCH OF CONCERN (Mar. 29, 2012), available at http://oba.od.nih.gov/oba/biosecurity/PDF/United_States_Government_Policy_for_Oversight_of_DURC_FINAL_version_032812.pdf. For reaction and discussion of this policy from the scientific research community, see Carrie D. Wolinetz, *Implementing the New U.S. Dual-Use Policy*, 336 *Sci.* 1525 (2012).

36. Sec'y Health & Human Servs., Charter, National Science Advisory Board on Biosecurity [NSABB Charter] (April 2012), available at http://oba.od.nih.gov/biosecurity/PDF/NSABB-Charter_Signed_2012.pdf. All federal advisory committees such as the NSABB terminate after two years unless renewed by the appropriate U.S. government official (for advisory committees created by a U.S. government official) or as otherwise specified by Congress (for advisory committees created by an Act of Congress). 5 U.S.C. App. 2, § 14.

37. NSABB Charter, *supra* note 36, at 1. Documentation of the NSABB's numerous activities and public meetings, as well as a library of previous NSABB publications, is available online. See NSABB Documents, NIH, http://oba.od.nih.gov/biosecurity/biosecurity_documents.html.

38. NSABB Member Roster, NIH, http://oba.od.nih.gov/biosecurity/biosecurity_voting_members.html. Fifteen federal agencies and departments also are represented on the NSABB through non-voting ex officio members. The NSABB Charter includes “public perspective” as an area of expertise that may be represented on the NSABB; the charter language, however, makes it clear that this is not a requirement for the composition of the NSABB membership roster. NSABB Charter, *supra* note 36, at 3-4.

biological agents,³⁹ these solicitations arguably have undermined public participation and interest in several ways. First, the NSABB tends to focus on questions or issues of a technical or abstract nature that are of greater import to the scientific community and research interests than to the lay public and the communities where such research occurs. In addition, public engagement is often limited by the details of the process. For example, public meetings may be limited to a specified physical location (e.g., a hotel in Bethesda, Maryland) during typical business hours, and communications (e.g., electronic or written correspondence) with decision-makers may be made through unofficial channels not open to public scrutiny. While this form of limited public engagement and participation may suffice for federal rule-making and policy-making on certain issues for the nation as a whole, a more direct form of public participation is required when addressing biological-based threats to the public as a matter of law and public policy at the state and local levels, where planning and policy decisions have a more direct and immediate impact on members of the lay public and the communities in which they live.

This “more direct” public participation should allow for greater engagement between scientists, government officials, and the lay public. As discussed in Part V, public participation of this nature in planning, decision-making, and policy-making has many benefits for the public’s welfare.⁴⁰

39. Public Consultation on Personnel Reliability and Culture of Responsibility Issues, 75 Fed. Reg. 76,997 (Dec. 10, 2010); Influenza Viruses Containing the Hemagglutinin from the Goose/Guangdong/1/96 Lineage, 77 Fed. Reg. 63,783 (Oct. 17, 2012) (request for information and comment).

40. Furthermore, federal decision-makers in the emergency management and public health emergency preparedness communities appear to agree with this approach and have urged state and especially local governments to include subject matter experts and community partners from the public, private, non-profit, and faith-based sectors in their emergency management activities. U.S. DEP’T OF HOMELAND SECURITY, COMPREHENSIVE PREPAREDNESS GUIDE 201: THREAT AND HAZARD IDENTIFICATION AND RISK ASSESSMENT GUIDE 9-10 (2012), available at www.fema.gov/library/viewRecord.do?id=5823 (“As the impacts of a threat or hazard affect more than the public sector, the jurisdiction should work with their whole community partners, including the private and nonprofit sectors and faith-based organizations, to gain a full understanding of all of the impacts to the community.”); Public Health Preparedness Capabilities, *supra* note 12, at 16-26 (“Community Preparedness” and “Community Recovery”).

V. ENGAGEMENT BETWEEN SCIENTISTS, GOVERNMENT, AND THE
COMMUNITY TO ADVANCE PUBLIC WELFARE

A. Government and Communities

The relationship between governments and the people over which they assert their authority is a fundamental question of political philosophy. In democratic societies, governments derive their legitimacy from the consenting public that they govern. This concept is enshrined in the preamble to the Constitution of the United States, which clearly states that it is “We the People of the United States” who “ordain and establish” this foundational source of the U.S. government’s authority, and that this consent of the people is given in part to “insure domestic Tranquility, provide for the common defense, [and] promote the general Welfare.”⁴¹ Public safety, public security, and public health arguably relate to domestic tranquility, the common defense, and general welfare;⁴² thus, the references to these concepts in the Constitution provide “the theoretical and legal authority for federally funded initiatives aimed at protecting and preserving the public’s safety, security, and health throughout the United States.”⁴³

41. U.S. CONST. pmbl.

42. Rose et al., *supra* note 24, at 86.

43. *Id.* The Spending Clause of the U.S. Constitution provides that “Congress shall have Power To lay and collect Taxes, Duties, Imposts and Excises, to pay the Debts and provide for the common Defense and general Welfare of the United States [.]” U.S. CONST. art. I, § 8, cl. 1. In their dissenting opinion in *National Federation of Independent Business v. Sebelius* (addressing the constitutionality of the Affordable Care Act (Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 119 (2010), amended by the Health Care and Reconciliation Act of 2010, Pub. L. No. 111-152, 124 Stat. 1029 (2010))), four Associate Justices of the U.S. Supreme Court recently summarized the history of the Court’s interpretation of “public Welfare” as used in the Spending Clause:

No one has ever doubted that the Constitution authorizes the Federal Government to spend money, but for many years the scope of this power was unsettled. The Constitution grants Congress the power to collect taxes “to . . . provide for the . . . general Welfare of the United States,” . . . and from “the foundation of the Nation sharp differences of opinion have persisted as to the true interpretation of the phrase” “the general welfare.” [James] Madison, it has been said, thought that the phrase “amounted to no more than a reference to the other powers enumerated in the subsequent clauses of the same section,” while [Alexander] Hamilton “maintained the clause confers a power separate and distinct from those later enumerated [and] is not restricted in meaning by the grant of them.”

The Court resolved this dispute . . . [in *United States v. Butler* in favor of] Hamilton’s approach and found that “the power of Congress to authorize expenditure of public moneys for public purposes is not limited by the direct grants of legislative power found in the Constitution.” Instead . . . the spending

In addition to the federal government's constitutional role in providing for the common defense and promoting general public welfare nationwide, the individual states also exercise an inherent "police power" to pursue activities aimed at protecting and preserving public safety, security, and health within their jurisdictional boundaries, both state-wide and locally.⁴⁴ As the authors have discussed elsewhere, emergency management and homeland security efforts at the federal, state, and local levels are among the aforementioned activities relating to public safety and security.⁴⁵

While governments have their responsibilities to protect and preserve general public welfare, the governed have civic responsibilities of their own, including an essential role in public affairs. As one commentator has noted:

Public participation is an ideal of democratic theory. Jean-Jacques Rousseau, a preeminent theorist of democracy and participation, envisioned a society wherein citizens would make the decisions that affect them. Rousseau believed that participation assures a government that is responsible to its citizens. Participation in government also educates people and develops citizens who are individually and socially responsible—those who know the difference between their individual preferences and the public interest. Through involvement in the decision[-]making that affects their lives, individual citizens become more free because they gain control over their lives.⁴⁶

Ideally, public participation may be defined as "the means by which the views of all parties interested in a given issue are integrated into the decision[-]making process[.]" with the "ultimate objective [of] mak[ing] and implement[ing] better decisions than would result in its absence."⁴⁷

power's "confines are set in the clause which confers it, and not in those of [Article I, Section 8 of the U.S. Constitution] which bestow and define the legislative powers of the Congress."

132 S.Ct. 2566, 2657-58 (2012) (Scalia, Kennedy, Thomas, and Alito, J.J., dissenting) (citations omitted) (quoting *U.S. v. Butler*, 297 U.S. 1, 65-66 (1936)).

44. Jorge E. Galva et al., *Public Health Strategy and the Police Powers of the State* (Supp 1), 120 *PUB. HEALTH REP.* 20 (2005); Lawrence O. Gostin, *Public Health Law in a New Century, Part I: Law as a Tool to Advance the Community's Health*, 283 *JAMA* 2837, 2841 (2000).

45. Rose et al., *supra* note 24, at 87.

46. Ellison Folk, *Public Participation in the Superfund Cleanup Process*, 18 *ECOLOGY L.Q.* 173, 178 & nn. 37-41 (1991) (notes omitted) (citing Rousseau's seminal 1762 treatise, *Du Contrat social ou Principes du droit politique* (The Social Contract, or Principles of Political Right), construed in CAROLE PATEMAN, *PARTICIPATION AND DEMOCRATIC THEORY* 22-24 (1970)); and JOHN STUART MILL, *ESSAYS ON POLITICS AND CULTURE* 186 (1962)).

47. Mimi L. Becker, *The International Joint Commission and Public Participation: Past*

Professor Mimi Larsen Becker has succinctly summarized the benefits of public participation in public decision-making processes as follows:

Decisions made with input from interested parties are more likely to result in an adequate specification of problems, an assessment of alternative solutions, and the integration of cultural and social values than would otherwise occur. Public participation can also provide an effective means for oversight of progress and provide for better government accountability during policy implementation. But the main objectives of public participation are: (1) to build public consensus regarding the nature of problems and the preferred solutions, and (2) to provide the basis for the sustained political will . . . to implement actions necessary to achieve joint objectives.⁴⁸

Furthermore, Becker argues that:

[p]ublic participation ought to involve two-way communication between the decision[-]maker and the public . . . [and] should be viewed as an integral part of a public policy process to be incorporated in the decision[-]making process from the earliest stages of policy initiation (problem definition) through the assessment, selection, implementation, and evaluation stages of a proposal or program.⁴⁹

Public participation in the planning and policy-making process has in fact had a long history in the United States that pre-dates the nation itself, particularly in the area of social policy at the local or community level.⁵⁰ In more recent years, this democratic ideal and American tradition has been codified into federal, state, and local legal authorities providing for public hearings and workshops, citizen panels and advisory councils, public notice and comment procedures, and citizen lawsuits in policy areas such as environmental protection,⁵¹ natural resources management (e.g., land and

Experiences, Present Challenges, Future Tasks, 33 NAT. RESOURCES J. 235, 237 (1993).

48. *Id.* at 238.

49. Becker, *supra* note 47, at 239 n.11 (citation omitted) (citing GARRY D. BREWER & PETER DELEON, *THE FOUNDATIONS OF POLICY ANALYSIS* 17-21 (1983)).

50. See, e.g., Mark Schlesinger, *Paradigms Lost: The Persisting Search for Community in U.S. Health Policy*, 22 J. HEALTH POL. POL'Y & L. 937, 938, 943-55 (1997) (noting that “[i]n every era of [U.S. history], policy makers have searched for the appropriate role for local communities in addressing social problems[]”; and reviewing how “prevailing notions of community as applied to health policy have changed” from colonial times through 1995); and Folk, *supra* note 46, at 179 & n.42 (citing ALEXIS DE TOCQUEVILLE, *DEMOCRACY IN AMERICA* 62-68 (J. Mayer ed. 1969, Bowen trans. 1862) (emphasizing that participation is a “tradition of democracy” that historically was “reflected in the New England town meetings described by Alexis de Tocqueville over 150 years ago”)).

51. See, e.g., Folk, *supra* note 46, at 179 n.42-46 (identifying provisions for public

water),⁵² community planning,⁵³ and food and drug safety.⁵⁴ Furthermore, the Community-Based Public Health (“CBPH”) model for disease prevention and health promotion has emerged in recent years, whereby partnerships between public health professionals and community-based organizations (“CBOs”) are formed to allow “the community whose health is the focus of the intervention [to] identif[y] and assume . . . ownership of the health problem by actively working together with health professionals throughout the various project phases.”⁵⁵

Several important limitations and criticisms of public participation in public affairs and the policy-making process have been identified in the literature. The democratic philosophies underlying effective public participation assume that the public participants will engage in an informed, educated, and rational public discourse,⁵⁶ consequently “favor[ing] those who both can and wish to articulate their concerns through reasoned analysis, skewing the conversation to be more suited to some members of the polity than others.”⁵⁷ Some critics have noted that the public often does not engage in reasoned analysis, and that public participation in government policy-making can have unintended consequences that are detrimental to

participation in various federal environmental statutes and discussing opportunities for public participation provided for in the Superfund cleanup process).

52. See, e.g., Becker, *supra* note 47 (considering the adequacy of the International Joint Commission’s public participation initiatives in implementing the Boundary Waters Treaty of 1909 and the Great Lakes Water Quality Agreement between the United States and Canada); Robert D. Comer, *Cooperative Conservation: The Federalism Underpinnings to Public Involvement in the Management of Public Lands*, 75 U. COLO. L. REV. 1133 (2004) (examining “the constitutional authority for cooperative conservation, or the sharing of federal authority with nonfederal entities in the management of public lands”).

53. See, e.g., Amy Widman, *Replacing Politics with Democracy: A Proposal for Community Planning in New York City and Beyond*, 11 J. L. & POL’Y 135, 176 (2002) (examining “whether the comprehensive planning process [in New York City] lives up to its ideal as a method of public participation”).

54. U.S. Food & Drug Admin., *Advisory Committees: Consumer Representatives*, www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/CommitteeMembership/ucm231782.htm.

55. Vence L. Bonham et al., *Community-Based Dialogue: Engaging Communities of Color in the United States’ Genetics Policy Conversation*, 34 J. HEALTH POL. POL’Y & L. 325, 332-33 (2009).

56. See *id.* at 331 (citing L. M. FLECK, *JUST CARING: THE ETHICAL CHALLENGES OF HEALTH CARE RATIONING AND DEMOCRATIC DELIBERATION* ch. 5 (Oxford University Press 2008) and J. S. FISHKIN, *DEMOCRACY AND DELIBERATION: NEW DIRECTIONS FOR DEMOCRATIC REFORM* 37 (Yale University Press 1993)); and Becker, *supra* note 47, at 239.

57. Bonham et al., *supra* note 55, at 332 (quoting Iris Marion Young, *Communication and the Other: Beyond Deliberative Democracy*, in *DEMOCRACY AND DIFFERENCE* 120, 123 (S. Benhabib ed., Princeton University Press 1996) (“[T]he norms of deliberation are culturally specific and often operate as forms of power that silence or devalue the speech of some people”).

public welfare. For example, Professor Frank Cross has argued that public perceptions of societal risks are “centrally tainted by cognitive limitations and biased or incomplete information,”⁵⁸ and that over-reliance on such public perceptions in government risk control policy could result in diversion of finite governmental resources away from “more authentic and significant” risks, higher private economic costs, and increased risks of dangerous or fatal errors.⁵⁹ Cross also argues that a number of justifications for limiting public participation in public policy-making exist:

1. That members of the public might not want government policy to closely reflect their risk perceptions;⁶⁰
2. That members of the public “might recognize the shortcomings of their own perceptions and choose to defer to scientific expertise in government policy”;⁶¹
3. That the United States (under its current Constitution) is built upon a representative democracy rather than a direct democracy;⁶² and
4. That public participation does not necessarily further true majoritarian democracy because “participation often degrades into a battle of unrepresentative private interest groups” and may have “a built-in bias which favors the affluent and reduces the democratic influence of ordinary citizens, especially the underprivileged.”⁶³

58. Frank B. Cross, *The Public Role in Risk Control*, 24 ENVTL. L. 887, 968 (1994).

59. *Id.* at 929-55. In conclusion, Professor Cross remarks:

Few individuals would support such institutionalization of ignorance. Yet when it comes to matters of risk and regulation, the public ignorance wears a cloak of value judgment that tries to legitimize its role. However, much of the public perception is ascribable to simple ignorance, and when value judgments are involved, they are not always noble ones worthy of government cognizance.

Id. at 968.

60. See *id.* at 951.

61. *Id.* at 951-52.

62. *Id.* at 951 (“We have a representative democracy, in which the people delegate decision[-]making authority to [elected] representatives. Thus, United States democracy does not imply the automatic transfer of public predilections into government policy.”); and *id.* at 953 (“It must not be forgotten that, even in the total absence of direct public participation, government decisions are ultimately made by the elected representatives of the people.”).

63. *Id.* at 954; see also Widman, *supra* note 53, at 176 (asserting that “[d]emographically homogenous groups may organize more easily and thus have more time to devote to political lobbying” and that “the community with more effective organization and leadership could be perceived by city agencies as more likely to take issues to the ballot box, thus subtly (and perhaps wrongly) convincing political representatives that the goals of the politically savvy group reflect those of the community as a whole.”).

These justifications resonate with those critics who have warned about the “deleterious result to administrative goals of efficiency, expertise and control” that may arise from extensive public participation in public policy-making.⁶⁴

More recently, however, some commentators have countered these criticisms of the role of public participation and public perceptions in policy-making with the argument that “[e]xpressions of assumptions, fears, hopes, beliefs, and concerns may or may not fit into a strictly reason-based framework, but may more authentically convey legitimate issues that are relevant to policy decision[-]making.”⁶⁵ Even in arguing against over-reliance on public perception in policy-making, Cross acknowledges that “[p]revention of public fear is one legitimate concern of government[.]” and that “[p]ragmatism compels the avoidance of policies, however theoretically sensible, when public perception would render those policies futile and wasteful.”⁶⁶

As discussed in Part V(C), public participation and community engagement in the governance of certain types of research is challenging but critical to ensuring that the public’s welfare is fully protected. Given the delicacies in developing such relationships, governmental authorities acting as an elected surrogate of the public can establish some parameters that both encourage the necessary public engagement and create certain baseline security standards to ensure a reasonable level of public health and safety.

64. Widman, *supra* note 53, at 142 (citing Nancy Perkins Spyke, *Public Participation in Environmental Decisionmaking at the New Millennium: Structuring New Spheres of Public Influence*, 26 B.C. ENVTL. AFF. L. REV. 263, 273 (1999)).

65. Bonham et al., *supra* note 55, at 332 n.4 (“While the role of reason should not be overemphasized in public deliberation, it should not be underemphasized either. Ultimately, public policies need to be justified and legitimated to all who are affected by those policies. The work of justification is necessarily the work of reason.”); see also Widman, *supra* note 53, at 141 (“Meaningful public participation focuses on the process, rather than the ultimate decision.”).

66. Cross, *supra* note 58, at 968; see also *id.* at 955 (citing Susan Hadden, *Public Perception of Hazardous Waste*, 11 RISK ANALYSIS 47, 51 (1991) and Branden B. Johnson, *Public Concerns and the Public Role in Siting Nuclear and Chemical Waste Facilities*, 11 ENVTL. MGMT. 571, 582 (1987)) (“However dubious and unsafe it may be to rely upon public perception, the decision[-]making process cannot exclude public opinion. Even with restrictions on public participation, the public will continue to influence government decision[-]makers, making its total exclusion from the risk regulation process impossible. Efforts to bar the public entirely from risk decision[-]making may produce only adversariness and litigation.”) (citations omitted).

B. Science and Government

As an institution built on democratic principles, the U.S. government seeks to engage the public on a broad level by informing the public of how it actively strives to improve the quality of life for all citizens by promoting the advancement of scientific discoveries, as outlined in the missions of HHS and especially NIH.⁶⁷ Generally speaking, this advancement occurs by the U.S. government making available public monies to academic and private institutions to pursue the identification of novel treatments in the fight against many different types of diseases. Scientific research is obviously a very technical field, but in order to represent the public's best interest, the U.S. government has developed a system where the value of scientific research conducted is gauged, measured, and evaluated by a peer-review system.⁶⁸ The U.S. government also has developed policies for the public dissemination of research that have successfully moved through the peer-review system and received federal funding:

The NIH Public Access Policy ensures that the public has access to the published results of NIH funded research. It requires scientists to submit final peer-reviewed journal manuscripts that arise from NIH funds to the digital archive PubMed Central upon acceptance for publication. To help advance science and improve human health, the Policy requires that these papers are accessible to the public on PubMed Central no later than 12 months after publication.⁶⁹

The U.S. government has been less successful at informing the public on issues related to ongoing research at various institutions and to how government agencies select promising funding opportunities. In the current peer-review process, the reviewers take on the responsibility of representing the public's best interest when deciding which research proposals to fund. However, these representatives of the public's best interest are highly skilled scientists with very technical backgrounds and whose perception of DURC concerns might differ from the average lay citizen. Greater community engagement and participation thus becomes essential for creating avenues of communication that lead to a better integration of scientific institutions within their communities.

67. U.S. Dep't Health & Hum. Servs., About HHS, <http://www.hhs.gov/about/index.html>; U.S. Nat'l Insts. of Health, About NIH, Mission, <http://www.nih.gov/about/mission.htm>.

68. See, e.g., NIH Peer Review Process, http://grants.nih.gov/grants/peer_review_process.htm; NIH Peer Review Policies & Practices, <http://grants1.nih.gov/grants/peer/>.

69. U.S. Nat'l Insts. of Health, National Institutes of Health Public Access, <http://publicaccess.nih.gov/>.

C. Science and Communities

1. Public Outreach and Information

The notion of community engagement in research is not new. The first major effort to codify best practices for scientific researchers to reach out to their communities began in the United States in October 1995, when the CDC and Agency for Toxic Substances and Disease Registry (“ATSDR”) partnered to establish the Committee for Community Engagement.⁷⁰ The work of this committee was completed in 1997 with the publication of the first edition of *Principles for Community Engagement*.⁷¹

The *Principles for Community Engagement* identifies a continuum of public participation.⁷² At the lower (more fundamental) end of this continuum is the concept of outreach, which is intended to improve the factual understanding of the community in an effort to dispel misconceptions and fear.⁷³ Outreach and public information sharing represent the critical foundation upon which all higher involvement models are built and requires the establishment of appropriate lines of communication that flow from scientists to community. Without successful communication, all other community engagement is impossible.⁷⁴ The unfortunate reality is that the natural inclination of the general public is to distrust the motivations and techniques for advanced research, particularly when it involves inherently dangerous materials, such as select agents.⁷⁵

70. U.S. DEP’T HEALTH & HUM. SERVS., CLINICAL AND TRANSLATIONAL SCIENCE AWARDS CONSORTIUM COMMUNITY ENGAGEMENT KEY FUNCTION COMMITTEE TASK FORCE ON THE PRINCIPLES OF COMMUNITY ENGAGEMENT, *PRINCIPLES OF COMMUNITY ENGAGEMENT* xv, NIH Publication No. 11-7782 (2d ed. June 2011), available at www.atsdr.cdc.gov/communityengagement/pdf/PCE_Report_508_FINAL.pdf.

71. U.S. CTRS. FOR DISEASE CONTROL & PREVENTION/AGENCY FOR TOXIC SUBSTANCES AND DISEASE REGISTRY (CDC/ATSDR) COMMITTEE ON COMMUNITY ENGAGEMENT, *PRINCIPLES OF COMMUNITY ENGAGEMENT* (1st ed. 1997), available at <http://www.cdc.gov/phppo/pce/>. A revised second edition of this document was published in June 2011. *PRINCIPLES OF COMMUNITY ENGAGEMENT* (2011), *supra* note 70.

72. *PRINCIPLES OF COMMUNITY ENGAGEMENT* (2011), *supra* note 70, at 8 (Fig 1.1).

73. *Id.* at 8.

74. Barbara A. Israel et al., *Review of Community-Based Research: Assessing Partnership Approaches to Improve Public Health*, 19 *ANN. REV. PUB. HEALTH* 173 (1998); Syed M. Ahmed & Ann-Gel S. Palermo, *Community Engagement in Research: Frameworks for Education and Peer Review*, 100 *AM. J. PUB. HEALTH* 1380 (2010); Vicki Marsh et al., *Beginning Community Engagement at a Busy Biomedical Research Programme: Experiences from the KEMRI CGMRC-Wellcome Trust Research Programme, Kilifi, Kenya*, 67 *SOC. SCI. & MED.* 721 (2008).

75. U.S. Dep’t Health & Hum. Servs., *National Select Agent Registry*, <http://www.selectagents.gov/>. Select agents are “biological agents . . . that could pose a severe threat to public health and plant health, or to animal or plant products.” About Us,

This distrust can be magnified when, because of public safety and security concerns, scientists and their regulators cannot be as forthright about the science being conducted, laboratories being utilized, or the types of research being conducted.⁷⁶ Lack of full disclosure makes any communications complicated and seriously hampers the ability of both researchers and community members to build appropriate collaborative relationships.⁷⁷

2. Community Consultation and Community-Based Participatory Research

The expansion of community engagement through outreach and information sharing can establish a framework that allows a two-way collaboration between the scientists conducting dangerous research and members of the general public who potentially may be affected by the research. To expand from a standard outreach program, the next step is to establish a system or forum for two-way communication. This inherently allows for community-driven feedback to be taken into the research program.

The best illustrations of two-way interaction between science and community occur in the context of Community-Based Participatory Research (“CBPR”). CBPR is defined as “a collaborative process that equitably involves all partners in the research process and recognizes the unique strengths that each brings[.]” where the research topic is of importance to the community and the research aims to combine “knowledge and action for social change to improve community health and eliminate health disparities.”⁷⁸ CBPR thus aims to establish a sustainable commitment between the research community and public to work in tandem to solve each other’s concerns and promote the objectives of both parties.

CBPR frameworks work best for community-based public health research endeavors. Establishing such a framework in the context of biodefense or cutting-edge infectious disease research is far more complex. The ability of the public to participate in the conduct of this research is extremely limited. Furthermore, federal grant spending for such programs

NAT’L SELECT AGENT REGISTRY, *supra* note 29.

76. Laura H. Kahn, *Biodefense Research: Can Secrecy and Safety Coexist?*, 2 *BIOSECURITY & BIOTERRORISM: BIODEFENSE STRATEGY, PRAC. & SCI.* 81 (2004); Andrew H. Fell & Patricia J. Bailey, *Public Response to Infectious Disease Research: The UC Davis Experience*, 46 *INST. FOR LABORATORY ANIMAL RES. J.* 65 (2005), available at http://dels-old.nas.edu/ilar_n/ilarjournal/46_1/html/v4601fell.shtml; James B. Petro & David A. Relman, *Understanding Threats to Scientific Openness*, 302 *SCI.* 1898 (2003).

77. See *supra*, note 55 and accompanying text.

78. *COMMUNITY HEALTH SCHOLARS PROGRAM, STORIES OF IMPACT* (2001), available at www.kellogghealthscholars.org/about/ctrack_impact_scholars_book.pdf.

is so restrictive that it does not allow for community engagement to be practicably considered within the context of the other burdensome requirements that researchers in such environments face.⁷⁹ Despite recent efforts to improve government oversight of dangerous research that utilizes federal grant funding,⁸⁰ the unfortunate reality is that little attention has been paid to the greater need for community engagement and consultation. Mechanisms to bridge the disconnect between scientists, government, and the lay public represent a significant yet necessary hurdle to continuing safe and efficacious discovery, particularly in the area of cutting-edge research.⁸¹

D. Scientists, Government Officials, and the Lay Public as Joint Community Partners: Enhancing the Multi-Stakeholder Interface

The preceding discussions in this Part make it clear that much misunderstanding and poor communication frequently exists between scientists, government officials, and the lay public. It is also clear from these discussions that enhancing the interface between these stakeholders poses a variety of challenges. In many instances, research is conducted without the surrounding neighborhoods and community being aware of its existence. Although this may occur for proprietary reasons (especially when the research is conducted by industrial and private-sector entities), a disconnect remains between the scientists conducting such research and the members of the surrounding community. Furthermore, scientists conducting research on dangerous biological agents may believe that their work benefits the greater good of society and thereby advances the public welfare and interests of their surrounding community, whereas members of

79. Gigi Kwik Gronvall et al., High-Containment Biodefense Research Laboratories: Meeting Report and Center Recommendations, 5 *BIOSECURITY AND BIOTERRORISM* 75 81-82 (2007), available at www.upmc-biosecurity.org/website/resources/publications/2007/2007_article_pdfs/2007-04-04-highcontainmentbioresearchlab.pdf.

80. See, e.g., U.S. GOV'T, *POLICY FOR OVERSIGHT*, supra note 35; U.S. GOV'T ACCOUNTABILITY OFFICE (2009), supra note 33; and U.S. GOV'T ACCOUNTABILITY OFFICE (2013), supra note 33.

81. Possible best practices to incorporate when designing such bridging mechanisms may be derived from recently-published reviews of public deliberation in decisions related to health research and policy. See e.g., Joanna E. Siegel, Jessica Waddell Heeringa & Kristin L. Carman, Public Deliberation in Decisions about Health Research, 15 *VIRTUAL MENTOR: AM. MED. ASS'N J. ETHICS* 56 (2013), available at <http://virtualmentor.ama-assn.org/2013/01/pdf/pfor2-1301.pdf>, and Kristin L. Carman et al., *THE USE OF PUBLIC DELIBERATION IN ELICITING PUBLIC INPUT: FINDINGS FROM A LITERATURE REVIEW*, AHRQ Publication No. 13-EHC070-EF (Rockville, Md., Agency for Healthcare Research and Quality Feb. 2013), available at www.effectivehealthcare.ahrq.gov/ehc/assets/File/Deliberation-Public-Lit-Review-130213.pdf.

that community may have difficulty understanding or accepting that the benefits of such research outweigh the risks.

A delicate approach is needed to enable productive conversations regarding the safety and security of people in communities in which research on dangerous biological agents takes place. In the international arena, active engagement is underway to establish fair policies to meet the security concerns of the public while providing assurances that scientists can continue to do their work without major interference from governmental authorities and members of the surrounding community. These international efforts are guided by a report on Biotechnology Research in an Age of Terrorism issued in 2004 by the National Research Council's Committee on Research Standards and Practices to Prevent the Destructive Application of Biotechnology.⁸² The scope of this report is much more broadly applicable to enhancing the partnership between scientists and government agencies to allow research to be conducted in a safe and secure environment with every freedom intact for scientists.

In the United States, some progress in this area has been made in the area of emergency preparedness and management with the adoption of a community-based, all-hazards approach to emergency response planning and preparedness at the federal, state, and local levels. However, there is still much room to delineate best practices for enhanced emergency preparedness that could better serve the interests of the public and science through enhanced communications, public policy initiatives, and laws, especially at the local level. This all-inclusive approach must also integrate threats beyond those perceived as clear and present dangers. Discussions between scientific institutions and leaders in the surrounding community need to consider worst-case scenarios that include accidental releases of biological pathogens.

1. Community-Based Participatory Planning, Decision-Making, and Policy-Making

As mentioned previously, public participation in public affairs and public-policy making has come under criticism because the public does not always engage in reasonable analysis and deliberation.⁸³ Because reasonable analysis is also fundamental to the philosophy of science and

82. COMM. ON RESEARCH STANDARDS & PRACTICES TO PREVENT THE DESTRUCTIVE APPLICATION OF BIOTECHNOLOGY, NAT'L RESEARCH COUNCIL, BIOTECHNOLOGY RESEARCH IN AN AGE OF TERRORISM (2004), available at <http://www.nap.edu/openbook.php?isbn=0309089778>.

83. See *supra*, Part V(A).

scientific inquiry, some commentators have concluded that the input of scientists and subject-matter experts is more valuable for governmental planning, decision-making, and policy-making efforts than input from the interested public.⁸⁴ These recommendations have been reflected in actual practice at times:

Government has often used the existence of these different approaches to the decision[-]making process as a reason for excluding the public. To the scientist or the economist, the public may be seen as emotional and irrational merely because it refuses to view situations from the same perspective. The public may want unreasonable solutions or may refuse to pay attention to scientific and economic analyses performed to support a decision.⁸⁵

Bringing together scientists, government officials, and members of the public in the process of planning, decision-making, and policy-making thus faces its share of challenges. Fortunately, there are precedents for such collaborations from the fields of public health, such as the application of CBPR principles to address public health issues,⁸⁶ and professionals and scholars in this field have even put together guides on how to apply CBPR principles and practices to influence the public policy process.⁸⁷

These principles can be applied to decision-making and policy-making related to research endeavors across a broad swath of disciplines. Unfortunately, their applicability to cutting-edge biodefense-based research is not as easily discerned given the necessity of separating the general public from dangerous organisms and the inherent security risks of providing complete disclosure of the research. However, just because the application of principles of CBPR and public participation is more challenging in this arena does not mean that it is impossible to achieve. The illustrative examples described in Part V(D)(2) are testament to this.⁸⁸

84. See, e.g., Cross, *supra* note 58, at 949-55, 968-69.

85. Folk, *supra* note 46, at 186.

86. James Krieger et al., Using Community-Based Participatory Research to Address Social Determinants of Health: Lessons Learned From Seattle Partners for Healthy Communities, 29(3) HEALTH EDUC. & BEHAVIOR 361 (2002); Israel et al., *supra* note 74; Siegel et al., *supra* note 81; and CARMAN ET AL., *supra* note 81.

87. Cassandra Ritas, Speaking Truth, Creating Power: A Guide to Policy Work for Community-Based Participatory Research Practitioners (July 2003), available at http://depts.washington.edu/ccph/pdf_files/ritas.pdf; MEREDITH MINKLER ET AL., COMMUNITY-BASED PARTICIPATORY RESEARCH: A STRATEGY FOR BUILDING HEALTHY COMMUNITIES AND PROMOTING HEALTH THROUGH POLICY CHANGE (2012), available at <http://www.policylink.org/atf/cf/%7B97C6D565-BB43-406D-A6D5-ECA3BBF35AF0%7D/CBPR.pdf>.

88. For a review of examples of public participation in another controversial area of

2. Illustrative Examples

a. Examples of Local and State Policy: Maryland

One local-level model for engagement between scientists, government officials, and the general public in the area of cutting-edge biodefense research has been initiated in Frederick County, Maryland, home to the United States Army Medical Research Institute of Infectious Diseases (“USAMRIID”) at Fort Detrick. In March 2010, the National Research Council issued a report recommending a “more proactive, two-way communication effort between USAMRIID and the surrounding community”⁸⁹ that could “build trust, alleviate concerns about community safety, and provide an opportunity for community members to participate in the continuous improvement of laboratory practices.”⁹⁰ In response to this report, the Containment Lab Community Advisory Committee (“CLCAC”) was established as a joint committee of the City of Frederick and the Frederick Board of County Commissioners in November 2010 and began meeting in late January 2011.⁹¹ The committee is composed entirely of Frederick County residents and has representation from the community, the City of Frederick, and the Frederick Board of County Commissioners.⁹² The stated purpose of the CLCAC is to:

- [1.] Foster two-way communication between the public and the operators of the high containment laboratories operating at Fort Detrick and elsewhere in Frederick County[;]

science, see Phil Richardson et al., *Public Involvement As A Tool To Enhance Nuclear Safety*, ENERGY STRATEGY REVIEWS (2012) (in press), available at <http://www.sciencedirect.com/science/article/pii/S2211467X12000375>.

89. DRAFT CHARTER, NAT’L INTERAGENCY BIODEFENSE CAMPUS, FORT DETRICK CMTY. ADVISORY COMM., available at <http://frederickcountymd.gov/documents/13/989/latest%20charter%20for%20NIBC%20CAC.PDF> (last visited Jan. 7, 2013).

90. NAT’L RESEARCH COUNCIL, EVALUATION OF THE HEALTH AND SAFETY RISKS OF THE NEW USAMRIID HIGH-CONTAINMENT FACILITIES AT FORT DETRICK, MARYLAND 59 (2010).

91. THE CONTAINMENT LABORATORY COMMUNITY ADVISORY COMMITTEE OF FREDERICK, MD., FIRST ANNUAL REPORT: JANUARY- SEPTEMBER 2011 3 (Oct. 11, 2011), available at www.cityoffrederick.com/DocumentView.aspx?DID=1071; News Release, Frederick County, Md., City of Frederick, Md., U.S. Army Garrison, Fort Detrick, & U.S. Army Medical Research Institute of Infectious Diseases, County, City & Fort Detrick to Form Containment Laboratory Community Advisory Committee (Sept. 28, 2010), available at <http://www.cityoffrederick.com/DocumentView.aspx?DID=1073>. The City of Frederick is the self-governing County Seat of Frederick County, Maryland, Md. Manual On-Line, <http://msa.maryland.gov/msa/mdmanual/37mun/frederick/html/f.html> (last visited Feb. 28, 2013).

92. THE CONTAINMENT LABORATORY COMMUNITY ADVISORY COMMITTEE OF FREDERICK, MD, *supra* note 91, at 3.

- [2.] Seek information about public concerns and ways to address those concerns[; and]
- [3.] Advise and make recommendations on behalf of the public to government, containment laboratory[,] and Fort Detrick officials regarding opportunities to improve any laboratory-related operational matters that may potentially impact public safety and health.⁹³

In its first two years of operation, the CLCAC has worked to establish robust communications between command-level staff at Fort Detrick and the surrounding community that has facilitated information sharing about the laboratory safety aspects of the base and the conveyance of questions and concerns from the public to military leadership at USAMRIID. At each meeting, new potential interfaces with the public are discussed, new avenues for rapid receipt and conveyance of public concerns are considered, and new partners are engaged to enhance awareness of the public health preparedness infrastructure that might be required to respond to a laboratory accident at USAMRIID or its surrounding private support laboratories.⁹⁴

While the CLCAC has been successful in fostering and building a structure for communications, some challenges have not yet been addressed. For example, the private laboratories operating in the area surrounding Fort Detrick are under the oversight of the Maryland Department of Health and Mental Hygiene (“DHMH”). Citing security concerns, DHMH has been unable to share with the public or CLCAC the identities of these laboratories working on select agents in Frederick County. This has impeded the ability of CLCAC to engage those laboratories in discussions related to safety and security in an effort to enhance the public’s safety, well-being, and awareness.⁹⁵

93. Containment Laboratory Community Advisory Committee Purpose, THE CONTAINMENT LABORATORY COMMUNITY ADVISORY COMMITTEE OF FREDERICK, MD., <http://www.cityoffrederick.com/index.aspx?NID=564>. A containment laboratory is one that “employs engineering controls for managing infectious materials in the laboratory environment where they are being handled or maintained. The purpose of containment is to reduce or eliminate exposure to laboratory workers, other persons and the outside environment to potentially hazardous agents.” Office of Research Facilities-Development and Operations, Policies and Guidelines-Section 1-2: Definitions, U.S Dep’t of Health & Human Servs., <http://orf.od.nih.gov/PoliciesAndGuidelines/BiomedicalandAnimalResearchFacilitiesDesignPoliciesandGuidelines/DRMHTMLver/Chapter1/Pages/Section1-2Definitions.aspx> (last updated Nov. 27, 2012).

94. Containment Laboratory Community Advisory Committee Minutes, THE CONTAINMENT LABORATORY COMMUNITY ADVISORY COMMITTEE OF FREDERICK, MD., www.cityoffrederick.com/Archive.aspx?AMID=37.

95. Audio Recording: Containment Laboratory Community Advisory Committee (Nov.

As a result of its work, the CLCAC issued a set of legislative proposals in 2012 that aimed to enhance laboratory safety throughout the State of Maryland.⁹⁶ These legislative proposals were formally introduced in the 2012 Regular Session of the General Assembly of Maryland as Senate Bill 758, with the sponsorship of three Maryland State Senators (led by one representing parts of Frederick County).⁹⁷ Senate Bill 758 included provisions that would have:

1. Established a Containment Laboratory Oversight Division within DHMH as the “sole unit of [Maryland] State Government responsible for oversight of containment laboratories in the State” with the authority to administer the Maryland state Biological Agents Registry Program and to “establish and enforce standards for the location, design, maintenance, and operation of containment laboratories in the State that protect the health and safety of laboratory workers, the public, and the environment from potentially harmful biological agents[]”,⁹⁸
2. Required the Secretary of DHMH to adopt regulations establishing various standards and requirements for containment laboratories in the State and establishing “uniform emergency notification and response procedures [for State and local emergency management agencies to] follow during emergencies involving containment laboratories;”⁹⁹

8, 2011), available at <http://www.cityoffrederick.com/Index.aspx?NID=407>.

96. Proposed Legislation for Integrating and Streamlining Oversight of BSL-3/4 Laboratories in the State of Maryland, THE CONTAINMENT LABORATORY COMMUNITY ADVISORY COMMITTEE OF FREDERICK, MD., <http://www.cityoffrederick.com/DocumentView.aspx?DID=1581>.

97. S.B. 758, 430th Gen. Assem., Reg. Sess. (Md. 2012); see also Department of Health and Mental Hygiene, Containment Laboratories Oversight: Hearing on S.B. 758 Before the S. Fin. Comm., Gen. Assem., 430th Sess. (Md. Mar. 15, 2012) (testimony of the Containment Laboratory Community Advisory Committee of Frederick, Md.), available at <http://www.cityoffrederick.com/DocumentView.aspx?DID=1582>.

98. S.B. 758, § 1, Gen. Assem., 430th Sess. (Md. 2012) (to be codified at MD. CODE. ANN., HEALTH-GEN. §§ 17-602(a)(2), -703). “Containment laboratories” were defined in the legislation to mean “any private or academic laboratory that qualifies as a Biosafety Level-3 Laboratory [i.e., working with biological agents that ‘are transmitted through the air’ and ‘can cause a potentially serious or lethal human disease’] or a Biosafety Level-4 Laboratory [i.e., working with biological agents that ‘may be transmitted through the air’ and ‘pose a high risk of life-threatening or lethal human disease for which no vaccine or therapy is available’].” S.B. 758, § 1, Gen. Assem., 430th Sess. (Md. 2012) (to be codified at MD. CODE. ANN., HEALTH-GEN. § 17-701(c)-(e)).

99. S.B. 758, § 1, Gen. Assem., 430th Sess. (Md. 2012) (to be codified at MD. CODE. ANN., HEALTH-GEN. § 17-704).

3. Established numerous licensing requirements for containment laboratories in the State;¹⁰⁰ and
4. Required the Governor of Maryland to establish a Containment Laboratory Advisory Committee to advise the Secretary of DHMH on matters related to the implementation of the above-listed provisions, and requiring that the membership of the Advisory Committee include representatives from several State government agencies, private and academic containment laboratories in the State, and at least “two members of the general public living in counties where private containment laboratories operate.”¹⁰¹

Although the Bill received an unfavorable vote in the Maryland Senate Finance Committee,¹⁰² the concerns raised received enough interest among legislators that DHMH “made a commitment to [the Maryland] Senate Finance and House Health and Government Operations Committees to establish and conduct [a Bio-Containment Laboratories Oversight W]orkgroup to study and make recommendations regarding the State[’s] regulation of biocontainment.”¹⁰³ Entirely a DHMH administrative initiative rather than an “official assignment” of the legislature, the workgroup has the stated purpose of assessing “community concerns regarding the health and safety issues associated with biosafety containment laboratories operating in the State and to identify any gaps that may exist in the State’s regulatory oversight of these facilities” and “the potential for the streamlining of containment laboratory regulations and the regulatory oversight performed by State government.”¹⁰⁴ The workgroup is scheduled

100. S.B. 758, § 1, Gen. Assemb., 430th Sess. (Md. 2012) (to be codified at MD. CODE ANN., HEALTH-GEN. §§ 17-705 to -711).

101. S.B. 758, § 1, Gen. Assemb., 430th Sess. (Md. 2012) (to be codified as MD. CODE ANN., HEALTH-GEN. §17-712) (emphasis added).

102. Department of Health and Mental Hygiene – Containment Laboratories – Oversight: Hearing on S.B. 758 Before the S. Fin. Comm., 430th Sess. (Md. 2012), available at http://mgaleg.maryland.gov/2012rs/votes_comm/sb0758_fin.pdf.

103. Robert A. Myers PhD, Dir., Md. Dep’t of Health and Mental Hygiene, Lab. Admin., Presentation to the Bio-Containment Laboratories Oversight Workgroup 1, 5 (Oct. 2, 2012) (transcript available at [http://dhmh.maryland.gov/laboratories/containment/Documents/Containment%20Workgrp%20Presentation%20\(10-02-12\).pdf](http://dhmh.maryland.gov/laboratories/containment/Documents/Containment%20Workgrp%20Presentation%20(10-02-12).pdf)); Courtney Mabeus, 2 CLCAC Members on Md. Oversight Committee, FREDERICK NEWS POST, Sept. 16, 2012, www.fredericknews.com/sections/news/display.htm?StoryID=140784; Md. Dep’t of Health & Mental Hygiene, Biocontainment Laboratories Oversight Workgroup, (last visited Feb. 26, 2013), <http://dhmh.maryland.gov/laboratories/containment/SitePages/Home.aspx>.

104. Myers, *supra* note 103, at 5-6.

to meet four times between October 2012 and April 2013 and will report its recommendations to the Maryland Senate Finance Committee and House Health and Government Operations Committee by June 30, 2013.¹⁰⁵

b. Examples of Local Law: Massachusetts

Because the Frederick County CLCAC and the Maryland work group are creations of administrative actions rather than of legislative acts, they are examples of community participation being adopted as a matter of local and state administrative policy rather than as a matter of law. The City of Boston, Massachusetts, on the other hand, has adopted community participation as a matter of law in its local codes and regulations relating to research on biological agents that pose a threat to public health and safety. These local legal authorities require the establishment of advisory committees with representation from local government, scientists familiar with the research being regulated, and “residents of neighborhoods which are or may be impacted” by the research being regulated.¹⁰⁶ They also require entities conducting regulated research to form institutional biosafety committees (“IBCs”) that include among their members community representatives “with no financial interest in the entity, from the community in which the laboratory is located or abutting communities.”¹⁰⁷ IBCs are to hold at least one public meeting each year in which “the type and nature of the biological research” conducted at the entity is reviewed before the

105. *Id.* at 6, 8; Dep’t of Health & Mental Hygiene, Biocontainment Workgroup Meetings, (last visited Mar. 12, 2013), <http://dhmh.maryland.gov/laboratories/containment/SitePages/Meetings.aspx>.

106. BOS. MASS. MUN. CODE §§ 17-9.1(c)(2) & 17-9.3 (establishing a Boston Biohazards Committee in recognition of “the need for community and scientific input to assist [local authorities] in carrying out their duties and responsibilities in regulating Recombinant DNA research, production and technology”); BOS. PUB. HEALTH COMM’N REG., BIOLOGICAL LABORATORY REGULATIONS §3.04 (establishing a Boston Biosafety Committee to be “composed of both scientific and community representatives to assist in regulating biological laboratories at BSL-3 and 4”); BOS. PUB. HEALTH COMM’N REG., GUIDELINES FOR THE IMPLEMENTATION AND ENFORCEMENT OF BOSTON PUBLIC HEALTH COMMISSION’S BIOLOGICAL LABORATORY REGULATION 15-16 (Mar. 29, 2007), available at www.bphc.org/boardofhealth/regulations/Forms%20%20Documents/guidelines_LabReg.pdf [hereinafter BOS. PUB. HEALTH COMM’N REG., GUIDELINES FOR BIOLOGICAL LABORATORY REGULATION].

107. BOS. PUB. HEALTH COMM’N REG., BIOLOGICAL LABORATORY REGULATIONS §2.03(a); BOS. PUB. HEALTH COMM’N REG., GUIDELINES FOR BIOLOGICAL LABORATORY REGULATION, *supra* note 106, at 8; See also BOS. MASS., MUN. CODE §§ 17-9.1(e) (requiring in part that institutional biosafety committees (“IBCs”) at laboratories using recombinant DNA in Boston “include at least one representative of the local community approved by the Commissioner and at least one non-doctoral person from the laboratory technical staff.”).

public.¹⁰⁸

Several other local jurisdictions in Massachusetts have established similar biosafety committees that include representation from the community in their respective membership rosters.¹⁰⁹

VI. AN INNOVATION IN PUBLIC HEALTH LAW: ENCOURAGING SCIENTIFIC PROGRESS AND PROMOTING PUBLIC WELFARE SIMULTANEOUSLY

Critics and proponents of public participation in government policy-making have acknowledged the role that the law can play either as a hedge against the “threat” of over-reliance on public participation or as a promoter of the “asset” of community involvement in public decision-making. For example, Professor Cross has argued that:

So long as public perception is so centrally tainted by cognitive limitations and biased or incomplete information . . . it cannot sensibly serve as the foundation of a risk control policy. The legal system must devise structures that minimize biasing influences of public perception and shift to greater use of regulation grounded in scientific data. This means that government policy of regulation and warning must become more strictly dependent upon the probabilistic reality of risks and not just upon public perception of these risks.¹¹⁰

As mentioned in Part V(A), however, Professor Cross also has acknowledged that public perceptions and value judgments cannot be entirely ignored in governmental risk control policy.¹¹¹ This is particularly true where the risks in question impact the public’s welfare at the community and individual levels, or the so-called “lifeforce” in which “an individual performs daily tasks and feels a connection to the local ecology” so that the individual “identifies with [it] and considers [it] home[.]”¹¹² A

108. BOS. PUB. HEALTH COMM’N REG., BIOLOGICAL LABORATORY REGULATIONS §2.03(c); BOS. PUB. HEALTH COMM’N REG., GUIDELINES FOR BIOLOGICAL LABORATORY REGULATION, *supra* note 106, at 8-9.

109. See *supra* note 33. These local jurisdictions include the City of Cambridge and the Towns of Amherst, Bedford, Belmont, and Tewksbury. Many biomedical research institutions and biotechnology companies are located in these localities. See generally, Massachusetts Biotechnology Council, Membership Directory, available at http://www.massbio.org/membership/membership_directory.

110. Cross, *supra* note 58, at 968-69.

111. See *supra* note 66 and accompanying text.

112. Derek Bayne, Bioregionalism and Environmental Regulation: A Policy Consideration for Future Environmental Reforms, 17 U. BALT. J. ENVTL. L. 1, 2-3 (citations omitted) (citing ROBERT L. THAYER, JR., LIFE PLACE: BIOREGIONAL THOUGHT AND PRACTICE 6 (2003)).

prime example of such a risk would be those experienced by communities that surround facilities that conduct dangerous scientific research.

Three decades ago, Professor Barry R. Furrow proposed that private tort remedies might be a good way for members of the community to regulate the hazards of modern scientific research, arguing that “common law nuisance entitlements can be redefined to cope with the risks of modern science and technology, then coupled with the use of complex injunctive decrees to provide a prophylactic means of governing hazard[.]” while also “provid[ing] an existing mechanism for asserting a risk-averse approach to new scientific and technological activities.”¹¹³ Although the purpose of this argument was to introduce public value judgments to regulation and public decision-making in a rational and organized fashion, a more direct (and less adversarial) form of public participation in regulating community hazards associated with dangerous research better serves the interest of protecting the public’s general welfare.¹¹⁴ Decision-makers in the emergency management community appear to agree with this more direct approach and have urged state and especially local governments to engage community partners in the public, private, non-profit, and faith-based sectors in their emergency management and preparedness activities.¹¹⁵

Enhanced communication and collaboration between scientists, government officials, and the lay public provides the best way to ensure that scientific research on dangerous biological agents intended to promote and protect the public’s welfare is conducted in a way that also promotes and protects the public’s welfare. Such multi-stakeholder interfacing provides a mechanism for scientists to better grasp the human and societal implications of their work and to better understand and empathize with the communities in which they work, for government officials to make informed decisions, and for community members to express their concerns and to learn how some of these concerns may be misplaced. Incorporating such multi-

113. Barry R. Furrow, *Governing Science: Public Risks and Private Remedies*, 131 U. PA. L. REV. 1403, 1466 (1983).

114. Nuisance suits are also notoriously difficult for plaintiffs to win, given the numerous elements and sub-elements necessary to make a prima facie case. See generally RESTATEMENT (SECOND) OF TORTS §§ 827-28 (1979); and George P. Smith, *Re-Validating The Doctrine of Anticipatory Nuisance*, 29 VT. L. REV. 687 (2005).

115. U.S. DEPT’ OF HOMELAND SECURITY, *THREAT AND HAZARD IDENTIFICATION AND RISK ASSESSMENT GUIDE: COMPREHENSIVE PREPAREDNESS GUIDE (CPG) 201 9-10* (Apr. 2012), available at www.fema.gov/library/viewRecord.do?id=5823 (“As the impacts of a threat or hazard affect more than the public sector, the jurisdiction should work with their whole community partners, including the private and nonprofit sectors and faith-based organizations, to gain a full understanding of all of the impacts to the community.”); Public Health Preparedness Capabilities, *supra* note 12, at 16-26 (“Community Preparedness” and “Community Recovery”).

stakeholder interfacing into the planning, decision-making, and policy-making processes arguably yields more robust plans, policies, and laws that are responsive to all aspects of public welfare.

Multi-stakeholder interfacing can be strengthened if supported by public policies with enforcing legal structures. Legislative acts or executive regulations similar to those from Boston and other Massachusetts localities¹¹⁶ would give administrative policy practices such as those from Maryland¹¹⁷ greater legitimacy as a democratic means to ensure that public welfare is protected through the regulation of DURC and other risky biomedical research occurring in communities. The legal structure provided by such acts and regulations also gives potency to such policy practices by effectively operationalizing the philosophical principles of public participation in ways that can be observed, evaluated, and modified (through subsequent legislative or regulatory amendments) if needed. In this way, legal tools can be used innovatively to harness a fundamental principle of democracy into an often under-utilized (if not entirely new) public policy strategy to address a modern (and relatively new) public health and safety issue of significant concern to communities throughout the United States and the world.

VII. CONCLUSION

With the continuing societal burdens posed by infectious diseases and the continuing threat of bioterrorism around the world, scientists have a compelling motive to continue investigating highly pathogenic diseases in the laboratory. However, scientists conducting such research need to better understand the implications of their research on members of the public, especially those living in the communities in which they work, as well as the legitimate interests of government officials to protect and promote public health and safety. Greater interfacing between scientists, government officials, and the lay public during planning, decision-making, and policy-making processes in areas of common concern can yield plans, policies, and laws that better protect all aspects of the public's welfare. Community-based participatory planning, decision-making, and policy-making can serve as a mediator between the interests of scientific advancement and public welfare, and laws and policies that facilitate such multi-stakeholder interfacing can facilitate the alignment of these interests. While such an environment can be difficult to establish, its value can be measured with each safely-developed medical countermeasure that prevents

116. See Part V(D)(2)(b), *supra*.

117. See Part V(D)(2)(a), *supra*.

or treats a probable future worldwide pandemic.

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